UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LATIESE MILLS, **Plaintiff,** **v.** **ATRIUM MEDICAL CORPORATION, et al.,** **Defendants.**	:	**Civil Action No. 17-12624 (KM)** **OPINION AND ORDER**

CLARK, Magistrate Judge

Currently pending before the Court is a motion by Defendants Atrium Medical Corporation and Maquet Cardiovascular, LLC (collectively, "Defendants") to exclude the opinions and testimony of Paul J. Cohen, M.D., Plaintiff Latiese Mills' Pathologist. [Dkt. No. 103]. Plaintiff Latiese Mills ("Plaintiff") has opposed Defendants' motion [Dkt. No. 105]. The Court has fully reviewed the papers submitted in support of and in opposition to Defendants' motion and decided the motion without oral argument pursuant to Fed. R. Civ. P. 78(b) and L. Civ. R. 78.1(b). For the reasons set forth below, Defendants' motion to exclude [Dkt. No. 103] is **DENIED**.

I. BACKGROUND

In March of 2013, Plaintiff underwent an abdominal hernia repair surgery at Pennsylvania Hospital in Philadelphia and was implanted with a "ProLite hernia mesh device" manufactured by Defendants. Dkt. No. 43, Am. Compl., at ¶¶ 16, 22. Plaintiff subsequently underwent multiple procedures to remove the mesh, including a repair of a "recurrent ventral hernia" and "reconstructive surgery due to the severe injuries suffered as a result of her mesh complications."

Id. at ¶ 18. Plaintiff alleges that a defect or undisclosed risk associated with the mesh caused her injuries in 2013, including a seroma (i.e., a fluid accumulation), infection, and scar tissue. Dkt. No. 103-1, Def. Br., at 1, 3. Plaintiff filed the instant personal injury action in state court claiming the mesh was defectively designed and that Defendants failed to warn about the risks associated with the product. Defendants removed the instant action to this Court on December 5, 2017. *See* Dkt. No. 1.

Discovery in this matter is complete and Defendants have moved for summary judgment. *See* Dkt. No. 102. Plaintiff submitted an expert report from one Dr. Paul J. Cohen, M.D. ("Dr. Cohen"), to establish specific causation, which Defendants now seek to exclude from the record by way of the instant motion.

II. LEGAL STANDARD

Under the Federal Rules of Evidence, the trial court acts as a gatekeeper in ensuring the relevance and reliability of all expert testimony. *See Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008). Fed. R. Evid. 702 governs the admissibility of expert testimony, and it provides that:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Rule 702 articulates three fundamental requirements: (1) the expert must be qualified to render his or her opinion; (2) the scientific process or methodology employed by the expert in rendering his opinion must be reliable; and (3) the expert's testimony must assist the trier of fact. *See Pineda*,

520 F.3d at 244. In short, an expert's conclusion must meet the "trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *See Padillas v. Stork–Gamco, Inc.*, 186 F.3d 412, 417–18 (3d Cir. 1999).

An expert is qualified to render an opinion when he or she "possess[es] specialized expertise." *Pineda*, 520 F.3d at 244 (quoting *Schneider*, 320 F.3d at 404). This qualification requirement is interpreted liberally, and formal education as well as a "broad range of knowledge, skills, and training" may provide the necessary qualifications. *Id.* (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994)). Consistent with this liberal policy of admissibility, courts have been cautioned not to exclude expert testimony merely because the court feels that the expert is not the best qualified or that the expert does not possess the most appropriate specialization. *Id.* (citing *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782 (3d Cir. 1996)).

The second prong of admissibility under Rule 702 requires a determination of the reliability, or inquiry into the underlying substance, of the expert's opinion. Expert testimony is "admissible so long as the process or technique used in formulating the opinion is reliable," and the principles and methods employed by the expert are applied reliably to the facts of the case. *Id.* at 247 (citing *Paoli*, 35 F.3d at 742); Fed. R. Evid. 702 advisory committee's note. An "expert's opinions must be based on the methods and procedures of science, rather than on subjective belief or unsupported speculation." *Paoli*, 35 F.3d at 742 (citations and internal quotations omitted). Thus, "the expert must have 'good grounds' for his or her belief." *Id.* (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993)). These good grounds must support each step of the

analysis and "any step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *Id.* at 745.

In determining the reliability of expert testimony, trial courts have been directed to consider the following *Daubert*-related factors: (1) whether the scientific method or theory can be or has been tested; (2) whether the method or theory has been subject to peer review and publication; (3) the known or potential rate of error when applied; (4) the existence and maintenance of standards and controls; (5) whether the method or theory is generally accepted in the scientific community; (6) the relationship of the technique or theory to methods or theories which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology or theory; and (8) the non-judicial uses to which the method or theory has been put. *United States v. Mitchell*, 365 F.3d 215, 234–35 (3d Cir. 2004) (listing factors under *Daubert*, 509 U.S. at 593–95, and *United States v. Downing*, 753 F.2d 1224, 1238 (3d Cir. 1985)). These factors, however, are neither dispositive nor exclusive. *See Pineda*, 520 F.3d at 248. Courts are entrusted to examine the reliability of the proffered expert testimony in a flexible manner.

Although the Court's inquiry into reliability is focused primarily "on principles and methodology, not on the conclusions that they generate," the Supreme Court has recognized that "conclusions and methodology are not entirely distinct from one another." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). A court cannot shy away from at least a limited review of an expert's conclusions "in order to determine whether they could reliably flow from the facts known to the expert and the methodology used." *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 152 (3d Cir. 1999); *see also In re TMI Litig.*, 193 F.3d 613, 682 (3d Cir. 1999) (finding that the district court did not abuse its discretion in excluding an expert's conclusion based upon a logical analysis of

the expert's testimony). If "there is simply too great an analytical gap between the data and the opinion offered," the Court may properly exclude the expert's testimony as "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Joiner*, 522 U.S. at 146.

Courts, however, should not exclude an opinion merely because there is an absence of literature on the precise issue as long as other factors demonstrate the reliability of the expert's opinion. *See Heller*, 167 F.3d at 154 (a medical expert need not "always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness" so long as there are good grounds, such as differential diagnosis, for the conclusion). Thus, other courts have found that the lack of scientific studies either proving or disproving the hypothesis of causality is not necessarily fatal to an expert's opinion. *See, e.g.*, *In re Ephedra Prod. Liab. Litig.*, 393 F. Supp. 2d 181, 188–89 (S.D.N.Y. 2005). Nevertheless, there must be good grounds for the expert's conclusions, and any gaps between the science and the conclusion must be bridged by scientific or medical knowledge. *See id.* at 189 ("Analogy, inference and extrapolation can be sufficiently reliable" when the proposed expert's conclusion is the "kind that a reasonable scientist or physician would make in a decision of importance arising in the exercise of his profession outside the context of litigation.")

The final prong of admissibility is the helpfulness, or fit. "Fit" in the context of Rule 702 refers to the helpfulness of the expert's testimony in assisting the trier of fact. This helpfulness requires a "valid scientific connection to the pertinent inquiry as a precondition to admissibility." *Daubert*, 509 U.S. at 591–92. The fit of an expert's opinion to the facts before a court "is not always obvious, and scientific validity for one purpose is not necessarily validity for other

unrelated purposes." *In re TMI Litig.*, 193 F.3d at 670 (quoting *Daubert*, 509 U.S. at 591). The issue of fit "is one of relevance and expert evidence which does not relate to an issue in the case is not helpful." *Id.* The standard for fitness is "not that high" but is "higher than bare relevance." *Paoli*, 35 F.3d at 745.

In the context of products liability litigation, plaintiffs often require the admission of expert testimony to evidence causation. Where there is little direct evidence proving an expert's conclusions or in a developing area of medicine and science, courts face particular challenges in determining whether the expert testimony is sufficiently reliable based upon the scientific and medical information presented to the court. Courts have noted that requiring experts to always "cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness" would "doom" all cases where the research on that subject was in its infancy. *Heller*, 167 F.3d at 155. Plaintiffs' experts must nevertheless demonstrate "good grounds" for all aspects of their proposed testimony, including "the methodology, the facts underlying the expert's opinion, the link between the facts and the conclusion." *Id.* (citing *Paoli*, 35 F.3d at 743-45).

III. DISCUSSION

With these legal standards in mind, the Court turns to examining whether Plaintiff proved, by a preponderance of the evidence, the admissibility of her expert's conclusion that:

> Based on my education, training, and experience practicing in the field of pathology, my familiarity with the scientific literature, my areas of expertise, and my review of the records in this case, I can state with a reasonable degree of medical certainty that, more likely than not, the source of the chronic infection was due to contaminated mesh material that was implanted on [March 27, 2013].

Dkt. No. 105-2, Exh. 20 ("Cohen Rep.") at 8.[1] Defendants make various arguments for why Dr. Cohen's opinions and testimony should be excluded: (1) Dr. Cohen is unqualified to opine on the cause of Plaintiff's injuries; and (2) Dr. Cohen's causation opinions are not the product of a sound methodology reliably applied to the facts of the case because (i) he does not show he employed a reliable methodology, (ii) the record contradicts Dr. Cohen's foundational premises, and (iii) Dr. Cohen fails to consider and rule out alternative causes. *See* Def. Br. at i.

Plaintiff opposes Defendants' motion, arguing that Dr. Cohen is qualified by training and experience to render an opinion on the source of Plaintiff's infection and Dr. Cohen's methodology of using the medical history, Dr. Schuricht's testimony, the timeline, and his specialized knowledge and experience to eliminate less likely causes of the infection is reliable and admissible under Fed. R. Evid. 702. *See* Pl. Br. at 3, 6.

The Court will first address Defendants' argument regarding Dr. Cohen's qualifications. Defendants assert that "Dr. Cohen is not qualified to opine that Plaintiff's ProLite mesh caused her injuries," especially where Dr. Cohen based his opinion "on his assumptions about the sterilization of ProLite mesh," because Dr. Cohen is "a pathologist who is not trained as a general surgeon or an infectious disease specialist, has not conducted any research in general surgery or surgery with mesh, and has never performed hernia surgery." Def. Br. at 6. Defendants further note that Dr. Cohen "spent only six hours working on Plaintiff's case prior to his deposition, two of which were writing his report," despite "the complexity involved in issuing specific causation opinions outside his field." *Id.* at 7.

[1] While both Defendants and Plaintiff annexed Dr. Cohen's report to their respective briefs, Plaintiff appears to have included the entirety of the report whereas Defendants included only excerpts. Thus, the Court will cite to Plaintiff's submission when referencing Dr. Cohen's report. *Compare* Dkt. No. 103-2, Exh. 2, at 45-48 (Defendants' submission) *with* Dkt. No. 105-2, Exh. 20 (Plaintiff's submission).

The Court disagrees with Defendants that Dr. Cohen is not qualified to opine on Plaintiff's injuries. Defendants do not challenge Dr. Cohen's qualifications as an anatomic pathologist, rightfully so, as he is board certified and has been practicing medical pathology for over thirty-five years. *See* Cohen Rep. at 2. Further, Dr. Cohen is the "Chair of Pathology at Yale's major affiliated Hospital in Bridgeport, Connecticut" where he reviews "cases of all types every working day, including both biopsies and resections of colorectal, gynecologic and thoracic lesions." *Id.* Contrary to Defendants' assertion, the Court finds that Dr. Cohen's leadership role in a hospital gives him broader knowledge and experience beyond his pathology background "upon which he could reliably draw conclusions about mesh-related complications in the human body." Def. Br. at 7; *see also* Dkt. No. 105-3, Exh. 21 ("Cohen Dep.") at 109:1-5 (". . . I didn't do any research, but just in my practice as a chairman of a medical department, we have quality rounds, and we go over all the surgical site infections. And in my experience, significant surgical site infections are rare."). Additionally, district courts "have repeatedly found pathologists qualified to testify about the pathology of mesh explants despite a lack of training in polymer science or in testing mesh products." *O'Bryant v. Johnson & Johnson*, Civ. No. 20-2361 (Shipp, J.), 2022 WL 7670296, at *7 (D.N.J. Oct. 13, 2022) (citing *Frankum v. Bos. Sci. Corp.*, No. 2:12-904, 2015 WL 1976952, at *24 (S.D. W. Va. May 1, 2015); *Sanchez v. Bos. Sci. Corp.*, No. 2:12-5762, 2014 WL 4851989, at *20 (S.D. W. Va. Sept. 29, 2014)).

Regarding Dr. Cohen's methodology, while the Court notes that Dr. Cohen did not review any pathology slides in formulating his expert opinions and testimony,[2] and such review is usually

[2] It appears from Dr. Cohen's deposition testimony that such review would have been impossible, as the surgeon who explanted the allegedly infected mesh did not send the mesh to the pathology lab to be inspected because he "was not suspicious that it was infected, . . . didn't think it would give us any additional useful information," and stated that "it would incur an additional cost." Cohen Dep. 139:19-24.

part and parcel of a pathologist's profession,[3] the Court is satisfied that Dr. Cohen employed a reliable methodology to reach his expert opinions. The Court admittedly agrees with Defendants that "Dr. Cohen's report provides little for Defendants and the Court to determine what methodology he employed." Def. Br. at 8. However, in his testimony, Dr. Cohen made clear that the question he was answering "was what caused Ms. Mills to have a significant abdominal infection that led to chronic illness" and in reaching his opinion that "to a reasonable degree of medical certainty . . . the mesh was infected" he reviewed "the [medical] records, the time course, [and] the findings by Dr. Schuricht, when he removed part of the mesh." Cohen Dep. 37:6-25. Dr. Cohen's testimony indicates a thorough review of the medical records and transcripts in this case, as well as an in-depth knowledge of the medical issues that underlie Plaintiff's claims in this case, and the Court concludes that his methodology passes muster under the applicable standards.

Finally, the Court disagrees with Defendants' arguments that the record contradicts Dr. Cohen's foundational premises and that Dr. Cohen fails to consider and rule out alternative causes. Instead, the Court agrees with Plaintiff that any disagreements between Dr. Cohen's conclusion and Dr. Schuricht's opinion as to the cause of Plaintiff's infection are better left for the trier of fact to decide. Further, in both his report and his testimony, Dr. Cohen demonstrates that he considered and ruled out alternative causes. In his report, Dr. Cohen indicated that "[c]ontamination from a surgical procedure that results in chronic infection" could "be from one of three sources" and then outlined in his "Opinions" section why two of those three sources were unlikely to be the originator

[3] *See Africano v. Atrium Medical Corp.*, No. 17-cv-7238, 2021 WL 2375994, at *4 (N.D. Ill. June 10, 2021) (defining a pathologist as one who "deals with the causes and nature of disease and contributes to diagnosis, prognosis, and treatment through knowledge gained by the laboratory application of the biologic, chemical, and physical sciences" and further noting that "[t]his specialist uses information gathered from the microscopic examination of tissue specimens, cells and body fluids, and from clinical laboratory tests on body fluids and secretions for the diagnosis, exclusion, and monitoring of disease") (quoting AMA Specialty Description, available at https://freida.ama-assn.org/specialty/pathology- anatomic-and-clinical).

here, thus considering and ruling out alternative causes for Plaintiff's infection. Cohen Rep. at 7-8. There were also numerous instances during his testimony wherein Dr. Cohen explained his reasoning for ruling out alternative hypotheses, such as infection from Staph aureus [Cohen Dep. 107:8-22] or the original Jackson-Pratt drain [Cohen Dep. 152:14-18]. Dr. Cohen appears to have used differential diagnosis[4] here in reaching his opinions, which courts have previously held is a valid and reliable method so long as there are good grounds for reaching the conclusion. *See, e.g.*, *Heller*, 167 F.3d at 154; *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 903 (7th Cir. 2007). The Court is satisfied based on his report and deposition testimony that Dr. Cohen has used sufficiently reliable and scientific grounds in reaching his opinions and—being mindful of the liberal policy of admissibility of expert testimony, *see Pineda*, 520 F.3d at 244—declines to exclude the opinions and testimony of Plaintiff's Pathologist Paul J. Cohen, M.D.

IV. CONCLUSION

The Court having considered the papers submitted pursuant to Fed. R. Civ. P. 78, and for the reasons set forth above;

IT IS on this 28th day of March, 2023,

ORDERED that Defendants' motion to exclude the opinions and testimony of Plaintiff's Pathologist Paul J. Cohen, M.D. [Dkt. No. 103] is **DENIED**.

s/James B. Clark, III
HONORABLE JAMES B. CLARK, III
UNITED STATES MAGISTRATE JUDGE

[4] Differential diagnosis "generally provides a framework in which all reasonable hypotheses are 'ruled in' as possible causes of a medical problem and some of these possible causes are then 'ruled out' to the extent scientific evidence makes it appropriate to do so." *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 903 (7th Cir. 2007). "A differential diagnosis satisfies a *Daubert* analysis if the expert uses reliable methods." *Id.* at 904.